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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,874	04/02/2004	Douglas Schein	115616	9059

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EXAMINER	
BOWERS, NATHAN ANDREW	
ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/815,874	SCHEIN ET AL.	
	Examiner	Art Unit	
	NATHAN A. BOWERS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *27-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26 and 47-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1-3, 7, 8, 11-22, 26 and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bacchi (US 5285657) and Cannon (US 20080032398).

With respect to claims 1-3, 7, 15 and 47-49, Bacchi discloses an apparatus for holding an organ or tissue during perfusion, storage, diagnosis and transport. A portable housing (Figure 2:63) provided for holding the organ is removably positioned within a tube frame assembly (Figure 2:60). As evidenced by Figure 2, the portable housing, the tube frame assembly, and the tubes within the tube frame assembly are aligned on the same horizontal plane. In addition to the portable housing, a refrigeration unit (Figure 1:20) a pumping unit (Figure 1:30) and a bubble detector (Figure 1:33) are positioned adjacent to the tube frame assembly. Fluid moving through the tubes positioned within the tube frame is moved through the refrigeration unit, pumping unit, bubble detector, and other unit operations. Figure 2 clearly depicts that the tubing (Figure 2:66) in the tube frame assembly is directly connected to the tubing in the portable housing via a plurality of openings (Figure 2:634 and Figure 2:631) formed on the portable housing. A plurality of tubes (Figure 2:6610, 661, 662) are provided for interaction with the openings of the portable housing. Bacchi, however, does not expressly indicate that the tubes are attached to the tube frame at respective predetermined positions that correspond to a location of the openings.

Cannon discloses a portable housing for culturing tissue cells. The portable housing includes a frame assembly (Figure 3) upon which a bioreactor is connected to fluid sources and other unit operations using a plurality of tubes (see Figure 6). Paragraph [0062] states that the tubing is secured to the frame assembly using clips or

any other fastener means capable of sufficiently securing the fluid path. From 6 of Cannon, it is apparent that each tube in the frame assembly is aligned at a position that corresponds with an opening of a bioreactor, supply reservoir, sensor, etc.

Bacchi and Cannon are analogous art because they are from the same field of endeavor regarding tissue treatment systems.

At the time of the invention, it would have been obvious to provide the tube frame assembly of Bacchi with clips and fasteners capable of holding each of the plurality of tubes at a desired position. This would have been a beneficial way to ensure that the flow paths do not become tangled or crushed during operation. Cannon is evidence that clips of this kind are well known in the art as effective means to organize fluid media tubes at predetermined positions within a frame assembly. One of ordinary skill would have additionally found it obvious to ensure that the tubes are positioned within the tube frame at locations that correspond with the openings of the Bacchi portable housing. One of ordinary skill would have recognized that inlet tubes should be positioned near an inlet opening, rather than on an opposite side of the tube frame, in order to reduce material costs and simplify the fluid supply system.

With respect to claim 8, Bacchi and Cannon disclose the apparatus in claim 1 wherein a pressure sensor capable of determining fluid pressure is connectable to the tube frame. Bacchi discloses the use of a control unit capable of detecting and regulating fluid pressure in column 4, lines 39-55 and column 5, lines 1-2.

With respect to claims 11 and 12, Bacchi and Cannon disclose the apparatus in claim 1 wherein the plurality of tubes in the portable housing are connectible to an organ (Figure 2:O). This is depicted in Figure 2.

With respect to claims 13, 14, 17 and 22, Bacchi and Cannon disclose the apparatus in claim 1. Furthermore, Bacchi teaches in column 8, lines 1-7 that the portable housing is reversibly attached to the tube frame assembly using "a bracket or the like" (Figure 2:601). The bracket is functionally equivalent to a clip, pin or snap in that it presses the portable housing tightly against the tube frame assembly. Screws are considered to be well known means that would serve to hold the bracket in place.

With respect to claims 18-21, Bacchi and Cannon disclose the apparatus in claim 1. Bacchi further teaches that the portable housing (Figure 2:63) is configured to be received by an organ transporter (Figure 1:10).

With respect to claims 18-21, Bacchi and Cannon disclose the apparatus in claim 17 wherein a pump is provided for transporting fluids through the plurality of tubes found in the portable housing and the tube frame. Bacchi describes the use of conventional peristaltic type pumps in column 4, lines 17-26.

With respect to claim 26, Bacchi and Cannon disclose the apparatus in claim 1. Plastic is considered to be a well known material suitable for the construction of a tube

frame. One of ordinary skill in the art would have been motivated to utilize plastic in the construction of the Bacchi tube frame due to its low cost and compatibility with known shaping techniques.

2) Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bacchi (US 5285657) in view of Cannon (US 20080032398) as applied to claims 1 and 17, and further in view of Hassanein (US 6046046).

Bacchi and Cannon disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly state that an organ supporting surface is located within the portable housing.

Hassanein discloses a portable device for preserving organs that comprising a holding chamber (Figure 5:206) in communication with perfusion means. Hassanein teaches in column 17, lines 3-20 that a soft pad (Figure 5:218) is provided for supporting an organ or tissue within an organ bath (Figure 5:212).

Bacchi and Hassanein are analogous art because they are from the same field of endeavor regarding organ holding apparatuses.

At the time of the invention, it would have been obvious to utilize an organ supporting surface in the apparatus of Bacchi. Hassanein teaches that soft foam surfaces conform to the contour of the organ transported thereon, and thereby prevent bruising and physical damage. Soft foam surfaces are inexpensive and prevent lateral motion of the organ within the portable housing, and are capable of retaining an organ bath.

3) Claims 6 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bacchi (US 5285657) in view of Cannon (US 20080032398) as applied to claims 1 and 17, and further in view of Fahy (US 5586438).

With respect to claim 6, Bacchi and Cannon disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly state that a filter is in communication with the plurality of tubes in the portable housing.

Fahy discloses the apparatus as previously described above. Fahy further indicates that a filter (Figure 1:121) is in communication with tubing adapted to supply and withdraw fluid to and from the organ. This is described in column 7, lines 15-22.

Bacchi and Fahy are analogous art because they are from the same field of endeavor regarding organ holding apparatuses.

At the time of the invention, it would have been obvious to include a filter device in the perfusion system disclosed by Bacchi. Fahy teaches that filter assemblies are beneficial because they remove undesirable particulates from fluids moving to the preserved organ. Fahy states that it is "very desirable to continuously filter perfusate to guard against any inadvertent introduction of microorganisms in any manner into the container."

With respect to claims 23-25, Bacchi and Cannon disclose the apparatus set forth in claim 17 as set forth in the 35 U.S.C. 102 rejection above, however do not

expressly state that a sensor is provided for detecting proper and improper connection between the tube frame and the organ transporter.

Fahy discloses a lid position sensor capable of detecting when the lid of the organ holding chamber is ajar. Column 13, lines 16-35 state that when the lid is determined to be in an undesirable position, the sensors will convey this information to an operator through the use of an alarm or visual display.

At the time of the invention, it would have been obvious to include a detection system capable of determining when the tube frame of Bacchi is improperly connected to the organ transporter. This would have been beneficial because it would have prevent possible damage to the organ resulting from mechanical failures resulting from improper connections. By ensuring that each component is properly connected to the other components, one would have been able to prevent tampering with the organ or excessive heat or contaminant infiltration.

4) Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bacchi (US 5285657) in view of Cannon (US 20080032398) as applied to claim 1, and further in view of Toledo-Pereyra (US 4186565).

Bacchi and Cannon disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly state that a bubble trap is provided within the tube frame.

Toledo-Pereyra discloses an apparatus for holding an organ (Figure 2:K) comprising a portable housing (Figure 2:14) defining one or more openings and a tube

frame (Figure 2:15) removably connectible to the portable housing. Column 1, line 51 to column 2, line 60 indicates that fluids located within the tube frame are transported to the portable housing using a system of tubes. The plurality of tubes in the tube frame are in communication with a plurality of tubes located within the portable housing in order to effectively introduce and withdrawn fluid to and from the organ. Furthermore, Toledo-Pereyra discloses that a bubble trap (Figure 2:17) is connectable to the tube frame and in communication with tubes located in the portable housing and the tube frame.

Bacchi and Toledo-Pereyra are analogous art because they are from the same field of endeavor regarding tissue treatment systems.

At the time of the invention, it would have been obvious to provide the tube frame of Bacchi with a bubble trap capable of treating fluid upstream from the portable housing holding the organ/tissue. As evidenced by Toledo-Pereyra, bubble traps are common components of an organ perfusion system, and fulfill the function of removing undesirable gases from a fluid stream before addition to the culture chamber. One of ordinary skill would have readily recognized the benefits of using a bubble trap when operating the Bacchi device, and would have been able to incorporate the bubble trap into the system of Bacchi in a predictable manner.

Response to Arguments

Applicant's arguments filed 10 August 2009 with respect to the 35 U.S.C. 103 rejections involving Toledo-Pereyra have been fully considered and are persuasive. These rejections have been withdrawn.

Applicant's arguments filed 10 August 2009 with respect to the 35 U.S.C. 103 rejections involving Bacchi have been fully considered but they are not persuasive.

Applicant's principle arguments are

(a) Bacchi does not disclose a tube frame holding tubes at predetermined positions, "each of the predetermined positions corresponding to a location of the one or more openings."

In response, please consider the following remarks.

It is agreed that Bacchi does not expressly indicate that the tubes are arranged within the tube frame in an ordered manner. However, the Cannon reference indicates that it is well known in the art to use clips to position tubes in a predetermined, desired location. In ordering the tubes of Bacchi according to the teachings of Cannon, one of ordinary skill would have found it obvious to position inlet tubes so that they correspond with the location of an inlet opening, and position outlet tubes so that they correspond with the location of an outlet opening. One of ordinary skill would have recognized this to be the most simple and effective arrangement.

(b) Bacchi discloses a single free-flowing tube rather than a plurality of tubes.

In response, please consider the following remarks.

At least two tubes are present in the Bacchi tube frame assembly. An inlet tube (Figure 2:661) carries fluid to the organ, and an outlet tube (Figure 2:662) carries fluid away from the organ. The inlet tube is not connected to the outlet tube, but instead terminates at a dispensing element (Figure 2:65).

(c) Bacchi does not disclose that the portable housing includes a connection device capable of interacting with the tube assembly.

In response, please consider the following remarks.

Bacchi teaches in column 8, lines 1-7 that the portable housing is reversibly attached to the tube frame assembly using "a bracket or the like" (Figure 2:601). One of ordinary skill would have recognized that it would have been obvious to provide a groove or some other similar feature on the portable housing to cooperate with the tube frame bracket. In describing the connection means, Bacchi includes devices that are "like" brackets, which would include connection features positioned on the portable housing. One of ordinary skill would have recognized that are connection features positioned on the tube frame and connection features positioned on the portable housing are functionally equivalent and obvious variants.

(d) The applied references do not suggest tubes that are horizontally aligned within the tube frame on the same plane.

In response, please consider the following remarks.

The claims do not require that the entire length of each tube must be aligned on the same horizontal plane. Although not expressly disclosed, the Bacchi tube frame would likely include tubes that each cross at least one common horizontal plane.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/Nathan A Bowers/
Examiner, Art Unit 1797